IMDRF International Medical Device Regulators Forum

GOOD REGULATORY REVIEW PRACTICES WORKING GROUP UPDATE

Working Group Chair: Melissa Torres
US Food and Drug Administration

GOALS

- The Good Regulatory Review Practices working group has focused efforts on harmonizing premarket requirements in alignment with the IMDRF strategic priority to improve the effectiveness and efficiency of premarket review.

- First completed work item:
  - IMDRF GRRP WG/N40FINAL: 2017 "Competence, Training, and Conduct Requirements for Regulatory Reviewers"
    - Defines a common set of conduct, education, experience, competence, and training requirements for premarket reviewers.

CURRENT WORK ITEM

- A NWIP was approved during the March 2017 IMDRF MC meeting which focused on revising GHTF/SG1/N68:2012 *Essential Principles of Safety and Performance of Medical Devices* to create a new/updated IMDRF document outlining essential principles that can be used as a foundation for creating a more harmonized premarket review process.
  - New requirements
  - New standards
    - ISO 16142-1:2016 *Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*
    - ISO/FDIS 16142-2 *Medical devices – Recognized essential principles of safety and performance of medical devices – Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards*

Current Progress

- Face-to-face working group meeting was held in Silver Spring, MD from July 10-13, 2017.
- WG used EU MDR, ISO 16142, and other jurisdictional requirements to update the Essential Principles.
- An initial draft of the Essential Principles document was created during the meeting.
- Draft document was circulated internally among WG participants and their jurisdiction.
  - Initial comments were received and incorporated.
- WG will begin working on guidance for the essential principles.

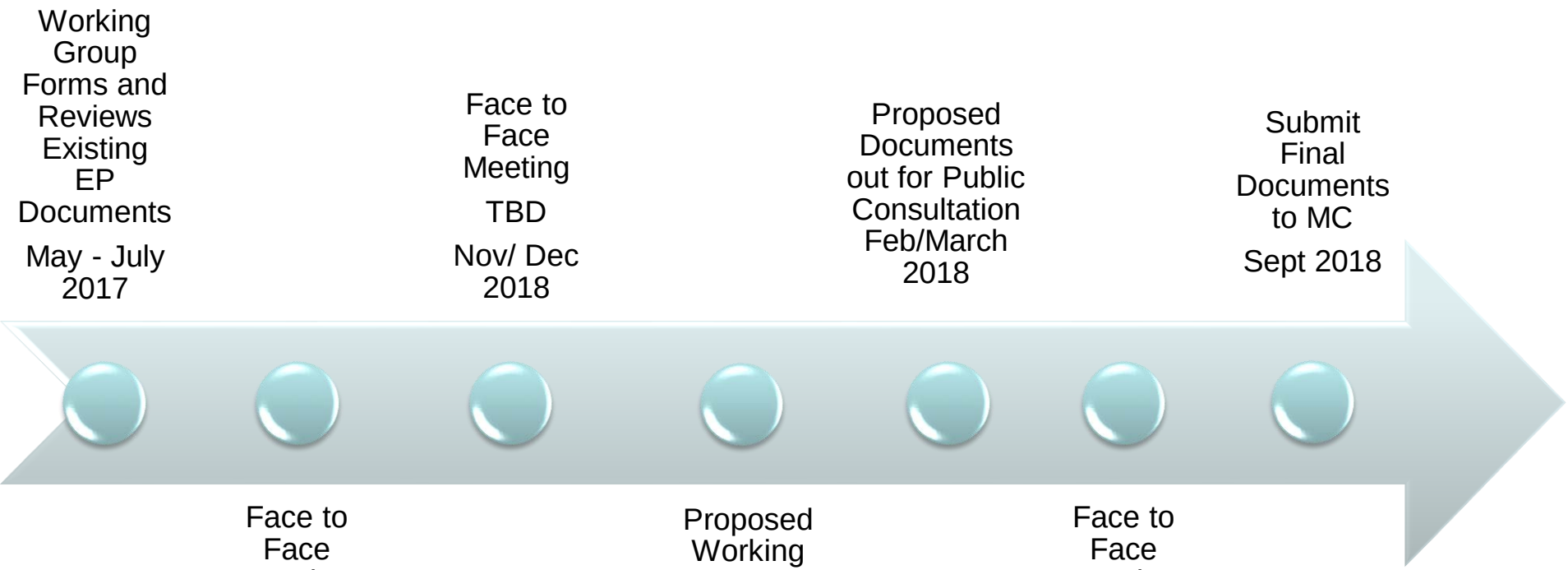
NWIP

- NWIP was submitted to IMDRF MC for consideration to revise GHTF *Label and Instructions for Use for Medical Devices* (GHTF/SG1/N70:2011)
  - Updating the labelling and instructions for use document in conjunction with the Essential Principles document is necessary given technological and regulatory developments since its original publication.
  - Revisions will be based on EU MDR, ISO 16142, and jurisdictional requirements.

NEXT STEPS

- If approved, GRRP WG will proceed with revision to GHTF/SG1/N70:2011 in conjunction with revisions to the Essential Principles (GHTF/SG1/N68:2012) aiming to have both documents completed for pubic consultation in Feb/March 2018.

TIMELINE


Working Group Forms and Reviews Existing EP Documents
May - July 2017
Face to Face Meeting
Silver Spring, MD
July 2017
Face to Face Meeting
TBD
Nov/ Dec 2018
Proposed Working Draft Documents Submitted to MC
Jan 2018
Proposed Documents out for Public Consultation Feb/March 2018
Face to Face Meeting TBD May 2018
Submit Final Documents to MC
Sept 2018
Working group teleconferences

THANK YOU